The Voice

FOR PREVENTION, TREATMENT, AND POLICY

National Center for Health Research

We are dedicated to improving the health and safety of adults and children by using research to develop more effective treatments and policies. The Cancer Prevention and Treatment Fund is our major program.

The Cancer Prevention and Treatment Fund

Our Cancer Prevention and Treatment Fund helps adults and children reduce their risk of getting cancer and helps everyone get the best possible treatment.

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What You Need to Know About Innovative Medical Treatments

The Wizard of Oz was just an ordinary man hiding behind a curtain — and is portrayed in the movie as an untrustworthy traveling salesman from Kansas with a magic elixir for whatever ails you. The Food and Drug Administration (FDA) tells us that the days of untested medical products are long gone, because the FDA ensures that all medical products sold in the U.S. are proven safe and effective. But whenever you consider an innovative, new "breakthrough" treatment that you see advertised, or hear about from your trusted physician, it is in your best interest to be a little cautious. Here's why: Knowing the standards used for FDA approval is key to making your informed medical decisions.

#1: Research studies submitted to the FDA are all paid for by the company that makes the product, and the company controls how the study is designed and the results they provide to the FDA. **#2:** Studies of patients are relatively short-term, even if the treatment is intended to help patients for years.

#3: New treatments do not have to be proven better than old treatments, even if they cost much more. "Innovative" doesn't necessarily mean better; it just means new and different.

Prescription drugs must be tested in clinical trials. The gold standard is 2 randomized, doubleblind controlled clinical trials. The purpose of these studies is to compare patients who get the experimental treatment to similar patients (same diagnosis, age, etc.) who either get a placebo or a treatment that is already FDA approved or considered the regular "standard of care" for that illness.

Having a comparison group that is as similar as possible to the treated patients is essential because some patients will live longer or recover faster than others, even if they get no treatment at all. Double blinding (when both the patient and researcher do not know which patients received the treatment vs. placebo) is important because people who think they are getting a new treatment may try harder to recover or perceive that they are improving because of wishful thinking rather than the medical product itself. Doctors may also treat the patients getting the experimental drug differently, too.

The standards for prescription drugs have lowered in recent years, due to industry pressure and Congressional pressure (often from legislators who receive generous donations from industry). In too many studies, the researchers measure physiological changes that don't really matter to patients, such as a biological "marker" that doesn't influence how they feel and may not affect their recovery or how long they live. A particularly egregious example was when the FDA approved Aduhelm for Alzheimer's Disease last year, despite evidence that the drug did not improve memory or other cognitive measures of the disease.

The standards are even lower for **medical devices**: a "reasonable assurance" of safety and effectiveness. And the FDA's view of reasonable is not so reasonable. This matters because all Americans (including you!) use medical devices, which include everything from band-aids and crutches, to contact lenses and wrinkle fillers, to implants that replace breasts lost to cancer, keep your legs walking, and your heart working. And 95% of them are allowed on the market without proof that they are safe or effective, if the FDA decides they are "substantially equivalent" to other devices that are already legally sold in the U.S.

"Substantially equivalent" is very subjective — as you can see in these photos— and many physicians and patients are shocked to learn that the new devices can be made from a different material and a different size, shape, or complexity compared to the old device.

Are these substantially equivalent?



If the device on the right is on the market, should the device on the left be sold without any proof of safety?

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News coverage of cosmetic surgery problems tends to focus on celebrities. Dr. Zuckerman was quoted in Good Morning America and Yahoo News about former NASCAR driver Danica Patrick, who became very ill from breast implants and is now recovering dramatically. Dr. Zuckerman was quoted in USA Today about model Bella Hadid, who regrets getting plastic surgery on her nose at age 14. We explained to reporters that teenagers are usually not psychologically equipped to make decisions that will permanently change their appearance and can have serious complications.

CPAP, BiPAP, and other ventilators made by Philips were recalled more than a year ago. Many patients haven't been informed and others can't live without them unless there is a replacement device they can afford. The FDA is now pressuring Philips to replace them. Dr. Zuckerman told Los Angeles Times how difficult it is for the FDA to take products off the market and how the process should be much easier than it is.

Valisure, an independent testing lab, was the first to notify the public about carcinogens in hand sanitizers, sunscreen, and dry shampoo. Why didn't the FDA identify these problems vears ago? Dr. Zuckerman told **Bloomberg** Law that the FDA does not do these simple tests and agency priorities are focused on faster approvals and other activities that pharmaceutical companies demand.

from patients

approval

pollution

In September, Los Angeles Times published a letter Dr. Zuckerman wrote in response to an article expressing concerns about the dangerous heat levels on asphalt school playgrounds, explaining that artificial turf is even hotter than asphalt and has other dangers as well. She told Los Angeles **Times** and **E&E News** that scientists have found that turf contains lead, PFAS, as well as other dangerous chemicals.

front-line role

Vaping vs. Smoking: The News is Surprising

Even if you don't use e-cigarettes, you probably know someone who does. And unfortunately, that someone might be a child in your family, or a friend who is trying to quit smoking and finding it is even harder to do while vaping than with traditional smoking cessation treatments.

The risks of e-cigarettes were big news in 2019, and then the COVID pandemic knocked it off the headlines. At first, kids being home all day made it harder for children and teens to find a place to hide their habit. Now they are back in school, and vaping is in the news again and the news is not good.

You might be surprised to learn that since 2017, e-cigarettes have become the most common first tobacco product for kids in grades 6-12, used by 77%. By 2019, more e-cigarette users were using their first tobacco product within 5 minutes of waking than for cigarettes and all other products combined. Median e-cigarettes use also increased from 3 to 5 days every month in 2014-2018, increasing to 10-19 days/month in 2021. There are many possible reasons for this dramatic increase, but one reason is that higher nicotine content in recent years is making vaping more addictive.

This year, more than 2.5 million U.S. middle and high school students reported current e-cigarette use, according to the U.S. government's 2022 National Youth Tobacco Survey. Responses to the online survey, conducted in January through May, found that 14.1% of high school students and 3.3% of middle school students admitted that they had used e-cigarettes within the previous 30 days. Of those, almost 28% reported using them daily and almost 85% reported using flavored e-cigarettes.

Vaping and the Brain and Heart

Tobacco use can damage DNA and increases the risk of lung cancer, breast cancer, and other cancers years later, but new research indicates that nicotine also affects children's brain development. A study of the brains of 9-10 year old children by researchers at the University of Nebraska found that children exposed to tobacco from cigarettes, e-cigarettes, or other sources had impaired brain development, including structural abnormalities that could affect schizophrenia, memory, mood and anxiety disorders, and drug dependence.

E-cigarettes can harm cardiovascular health in ways similar to cigarettes but also in other ways, such as leaky blood vessels which can lead to inflammation, edemas, and heart attacks. Studies suggest that if someone were to smoke both e-cigarettes and cigarettes, using both would increase their risk of cardiovascular disease even more than if they were to use just one or the other of these tobacco products.

Although e-cigarettes are smokeless, they result in increased concentrations of volatile organic compounds (VOCs) and airborne particles, both of which are potentially harmful when inhaled.

Research shows that most children who vape use disposable vaping pens, and the most common brands

are Puff Bar, Vuse, and Hyde. The FDA has warned Puff Bar that they aren't authorized to sell nicotine products even if they aren't made with tobacco. The agency also ordered Hyde to stop selling e-cigarettes because the company was not authorized to sell fruit-flavored e-cigarettes that were not proven to have a benefit to adult users that would outweigh the risks to children and teens.

Days after those warnings, the FDA warned 5 other e-cigarette companies to stop selling e-cigarettes that look like toys such as glow sticks, Nintendo Game Boys, and walkie-talkies, or to imitate foods such as popsicles. It isn't just that these make the products look appealing to children; the bigger problem is that the appearance of these products fools parents, teachers, and others in supervisory roles who are unaware that the child is vaping.

Why did this Epidemic Happen?

We are glad that the FDA is going after those companies, but we wonder what took so long and how effective the agency will be in stopping an epidemic that has hooked children on nicotine and kept adults addicted.

In 2010, a court ruled that the FDA could regulate e-cigarettes as tobacco products, but it wasn't until 2016 that the FDA banned the sale of e-cigarettes to anyone under the age of 18 and to require all e-cigarettes that were sold after February 15, 2007 to be reviewed by the FDA to determine whether they are safe. Companies were to be given from 18-24 months to prepare their applications.

However, in 2017, President Trump appointed a new FDA Commissioner, Dr. Scott Gottlieb, who defended the safety of e-cigarettes and decided to delay implementing the rules until 2022. As the epidemic of e-cigarette use among youth became obvious, in 2018 Commissioner Gottlieb threatened to crack down on the advertising of e-cigarettes to children under 18, but found that online sales and ads are very difficult to restrict. Commissioner Gottlieb resigned in 2019, and in that same year a federal court ruled that the FDA must implement regulations in May 2020 instead of 2022.

A federal court order required vape and e-cigarette companies to submit marketing applications to the FDA by September 2020, and their products were allowed to stay on the market for up to 1 year while the FDA reviewed their applications. In October 2021, the FDA authorized the marketing of three vaping products (Vuse Solo products), but rejected some flavored products from that same brand.

The FDA has now issued thousands of warning letters to companies that were not obeying the law, but many of these products are still being sold. The FDA also rejected the applications for more than 1 million flavored vape products. However, the FDA has not yet made a decision about all the applications it has received, and those also remain on the market. And, children and adults continue to erroneously believe that vaping is much safer than smoking.

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We're Speaking Up!

As a think tank, we frequently share our views with policymakers, government leaders, partner organizations, and health agencies, such as the FDA and the Environmental Protection Agency (EPA). You may wonder what these comments have to do with you, or how you are affected by our work. Every day, we testify and share research on your behalf, through written or oral testimonies regarding patient and consumer safety. Here are a few examples:

ance

In one of the several FDA Advisory Committee meetings on questionable cancer drugs in 2022, NCHR President Dr. Diana Zuckerman testified at a September meeting about the safety and effectiveness of Pepaxto for multiple myeloma. She expressed concern for patients who wanted a new treatment, but agreed with the FDA's scientific findings that compared Pepaxto to other treatment options. Pepaxto shortened patients' lives by several months and resulted in higher death rates. She pointed out that the company chose shortcuts rather than an appropriate research study, and continued to market the drug despite the evidence. The Committee agreed with us, voting 14-2 that the evidence does not indicate that the benefits outweigh the risks.

Makena was approved by the FDA through the accelerated approval pathway in February 2011 to reduce the risk of preterm birth. It was allowed to be sold while the company conducted better studies to confirm that it worked; but when the research was completed in 2020 it showed that Makena did not work. When FDA announced that approval would be rescinded, the company appealed the decision. In October 2022, NCHR Senior Fellow, Dr. Ealena Callender testified at an FDA Advisory Committee about the lack of evidence for the drug. She encouraged the committee to recommend withdrawing approval of Makena and taking the drug off the market. The Committee agreed, voting 14-1 to rescind approval.

Lou Gehrig's Disease

In March before an

FDA Advisory Committee about the safety and effectiveness of Relyvrio to treat amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's Disease. She expressed our concerns about the quality of the clinical trials conducted. One trial had no control group, and most patients dropped out after a year! In another study, many patients in the treatment group dropped out of the study but were still counted as surviving due to taking the drug. The Advisory Committee voted against approval. Despite the lack of new evidence, the FDA reconvened the Advisory Committee in September 2022, due to pressure from well-connected patients and patient groups. Dr. Zuckerman again testified at the meeting, expressing her continued concern that the research results did not meet FDA criteria of evidence that the product worked, and that there was no justification for approving an unproven drug when two other treatments were already on the market. Despite the concerns of FDA scientists and statisticians, the FDA approved the drug later that month.

In October 2022, NCHR praised the EPA's decision to designate PFOA and PFOS as "hazardous substances" since these chemicals are endocrine disruptors that can cause serious health problems. This change will hold companies responsible for removing these substances from their products. We also strongly urged the EPA to work with independent researchers and other federal agencies to develop a common definition for PFAS. We emphasized the need to classify these substances based on parameters such as structure and exposure data, because these changes in classification will protect the public health and our environment.

In October 2022, we submitted a public comment to the U.S. Preventive Services Task Force (USPSTF) in response to their guidelines about screening for depression and suicide risk in asymptomatic adults. We concluded that there was not enough evidence that the benefits of screening outweigh the risks for individuals who have no symptoms. We are especially concerned that primary care physicians that would do the screening do not have adequate expertise to recommend appropriate treatment and were likely to prescribe psychotropic drugs that could do more harm than good. Screening for suicide would be important if it were effective, but we agreed with the Task Force that there is no evidence that screening for suicide would be effective. We stated that additional research is needed to identify patients at risk of suicide, determine the most effective psychotherapy for managing patients with suicidal thoughts, and reduce the stigma associated with suicidal thoughts and treatment.

Diversity and Medical Care

Pulse oximeters are used to measure patients' oxygen levels. They have been in the news because of the clear evidence that they are less accurate for people with darker skin, which became obvious with COVID patients. In November 2022, NCHR Senior Fellow Dr. Ealena Callender told an FDA Advisory Committee that the lack of accuracy is a major medical problem and needs to be corrected. The readings affect medical decisions, and inaccurate readings can lead to fatal consequences. In their validation studies, Dr. Callender urged the FDA to require manufacturers to include individuals with a broad range of skin pigmentations. She pointed out that labels indicating possible inaccuracy for darker-skinned patients are not sufficient to save lives.

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How VALID Are Those Medical Tests?

Doctors and patients rely on many different kinds of medical tests to make treatment decisions and to develop prevention strategies. Some tests are developed in labs rather than by companies, but **the tests made by companies are evaluated by the FDA and those developed by labs are not.** These are widely used to diagnose diseases such as COVID-19, cancer, prenatal birth defects, and genetic vulnerability to cancer and other potentially lifethreatening diseases or conditions. Approximately 3.3 billion labdeveloped tests are used by doctors each year to guide medical decisions, so it worries many experts that these tests are not vetted by the FDA or any other independent reviewers.

Obviously, inaccurate results can be extremely harmful, if they result in unnecessary surgery or other inappropriate medical decisions. For example, a *New York Times* review found that the five most common prenatal genetic tests performed were incorrect 85% of the time, and yet they are advertised as "reliable" and "highly accurate." One test for Prader-Willi syndrome, a very serious condition that can cause seizures and makes it unlikely that an adult can live independently, was found to produce a false-positive result more than 90% of the time. A 2022 Washington Post investigation found that a Chicago-based lab produced COVID PCR tests that missed 96% of positive COVID cases, resulting in the spread of infection. This lab collected \$187 million in federal funds, over the course of 15 months during the pandemic before federal regulators suspended their license to operate. Based on the current lack of FDA oversight, companies can legally develop and sell these important tests without physicians or patients realizing how inaccurate they are.

Legislation has been introduced to address these shortcomings, but the solution is not as effective as it could be. The VALID Act, which is an acronym for "Verifying Accurate Leading-edge IVCT Development", was introduced by Senators Michael Bennet (D-CO) and Richard Burr (R-NC), and Representatives Diana DeGette (D-CO) and Larry Bucshon (R-IN). It would give the FDA the authority to regulate the riskiest lab-developed tests. The bill would establish a risk-based framework to review new tests before they are approved for use. It would also ensure the same standards are in place regardless of whether the test is developed by a lab or a company. However, these standards would be low for what the FDA considers "low-risk" and "medium-risk" tests, and the higher standards would focus instead on only the highest risk tests, such as those diagnosing cancer. For example, it is not clear if the FDA would regulate genetic tests that warn patients that they are likely to develop specific types of cancer or other serious diseases, even though such a test result could convince the patient to undergo irreversible surgery, such as a mastectomy or stomach removal.

In addition, the current version of the bill does not evaluate any of the 200,000 different lab-developed medical tests that are currently on the market and would even bar the FDA from reviewing those "grandfathered" tests in the future. That loophole and the lack of rigorous evaluation of moderate risk tests are crucial components of the VALID Act that need to be modified to ensure the tests with the greatest potential to cause harm from an inaccurate result undergo the greatest amount of scrutiny and review. Working with our partners in the Patient, Consumer, and Public Health Coalition, we have repeatedly urged Members of Congress to prioritize these needed reforms. We will continue to work with Congress to ensure that if the VALID act passes, it will protect patients from inaccurate tests.

Update on our Long COVID Project

Our project on Long COVID celebrated its one-year anniversary with a conference in Washington, D.C. that brought together health professionals, researchers, and patients in-person and remotely on October 3. It was a wonderful success, as shown by the energy and enthusiasm in the room as well as the anonymous evaluations from participants. Here are two examples.



For more information about our speakers (shown above), see https://www.center4research.org/long-covid-conference/

From a physician: This conference was a needed inspiration in bringing together colleagues and patients, working in a unified fashion to solve the intense and myriad problems brought on by Long-Covid. The material presented was professional and free of all commercial bias, and helped us see where we stood clinically in relation to others doing similar work around the country. It gave us treatment and management ideas that we can pass along immediately. The patient stories added insight into the lived experiences of Long-Covid as well, increasing my commitment to focus on this condition.

The very next day after the meeting, I was able to share knowledge with more than 50% of my patients regarding what I had learned. This was continued throughout the week. Patients were inspired to know the meeting had happened, and encouraged by the collaboration and insights. All participants with whom I spoke after the meeting voiced the hope that we would be able to repeat this event at least yearly, and perhaps have some virtual forum in-between. These types of gatherings are critical as we work to improve the lives of severely affected individuals, suffering from a condition for which there is still tremendous medical and social misunderstanding.

From a patient: I got COVID at the beginning of the pandemic. After a few weeks, when I should have recovered from "the worst flu I have ever had", I was still unwell. Eventually I was referred to a long COVID clinic but the clinic later closed. It was discouraging to go back to our primary providers for help.

The conference gathered people of science who took long COVID seriously, who articulated how harmful it could be to tell someone dealing with long COVID that they were "fine." The clinicians were encouraging — both in pushing me to find knowledgeable long COVID help, and in terms of doing whatever I can to improve my symptoms. The stories of the speakers who are living with long COVID were sadly familiar, which in its own way was validating.

It was also very helpful for me to identify the doctors and physical therapists who could be trusted sources for information. I came away knowing that there were people of medicine and science who were taking long COVID seriously, and were applying their considerable intellectual gifts to addressing their challenge. I was grateful for the opportunity to learn from the conference participants and am carrying what I learned with me as I advocate and work for my recovery.

Innovative New Medical Treatment (Cont'd)

The devices that are allowed to be sold as "substantially equivalent" are almost never required to be studied in clinical trials. Pictures really are worth a thousand words, which is why we are showing you two examples of the devices that the FDA considered "substantially equivalent." If you don't think it is a good idea to compare "apples and oranges," you'd be shocked by how many thousands of devices get on the market that way every year. If you're wondering about implanted devices in your body and whether they were allowed on the market as substantially equivalent, feel free to contact us at info@center4research.org.

Are these substantially equivalent?



Only the highest-risk medical devices — about 5% — are required to be tested in clinical trials. That doesn't make sense, since all prescription drugs must be tested in clinical trials, even those considered the lowest-risk medications.

Unfortunately, the standards are also low for these highest-risk medical devices — even for potentially life-saving devices because often their studies do not have a comparison group of patients. One example is when a device was studied on depressed adults and the patients said that their symptoms of



depression had lessened. But, without a comparison group it is impossible to determine whether those reported improvements were any different from patients who were untreated, or who tried simple strategies such as exercise or vitamins.

We have worked with Congress and the FDA to improve the standards for medical products since our founding in 1999. It is challenging work, but we've made progress thanks to our supporters; the patient and consumer advocates that we work with; and the health professionals, policy experts, and Members of Congress and their staff who are making their voices heard. With the help of excellent reporting by many journalists, we've also educated the public about these FDA loopholes.

Leaving a Legacy



With the support of his family, friends, and colleagues, we are honored to again offer an internship in honor of **Jack Mitchell**, a former federal investigator for the Senate and the FDA who helped to pave the way for government regulation of the tobacco industry by securing the cooperation of a key whistleblower. He was the director of health policy at NCHR when he passed away in 2019 from non-Hodgkin's lymphoma. Prior to his position at NCHR, he was also a top adviser to officials at U.S. Department of Health and Human Services, the National Science Foundation and the Office of the Special Inspector General for Afghanistan Reconstruction.



that pertain to the safety and effectiveness of medical and consumer products. He testified before the FDA, assisted with drafting public comments to federal agencies, updated web articles to include the latest research-based information and policy issues on numerous issues including smoking, cancer treatments, and FDA standards. James graduated in 2017 from the College of William & Mary and is currently a second-year medical student at George Washington School of Medicine and Health Sciences, where he is pursuing a scholarly concentration in Health Policy and exploring a career in oncology.

We are proud to offer the Janice Bilden Cancer Prevention Internship in 2023, thanks to a generous donation from her daughter Holly Bilden-Stehling.

Our 2022 Jack Mitchell Policy Intern was James Castro Agueta, who focused on a range of health policy issues

Holly tells us that her mom "loved to laugh, have fun and help her family in any way she could. Mom was my best friend and my Matron of Honor. However, cancer took a devastating toll on her family. She lost 2 sisters and 2 brothers to cancer — all different types of cancers, but all with the same outcome. Mom also died from cancer. I am glad to have the opportunity to have an internship named in honor of my Mom that will help train a young professional to help others to prevent cancer. I believe wholeheartedly that prevention is the only sure way to save lives and prevent the type of pain my Mom felt, and in losing her the type of pain we feel everyday."



Shahmir Ali

Shahmir Ali was our 2022 Janice Bilden Cancer Prevention Intern. Shahmir holds a BA in public health and political science from Johns Hopkins University, and soon after his internship he completed his PhD at the NYU School of Global Public Health. His work at NCHR focused on cancer prevention strategies involving nutrition and exercise, smoking cessation, prostate cancer screening options, as well as preventing liver cancer through testing and treatment for Hepatitis B and Hepatitis C.

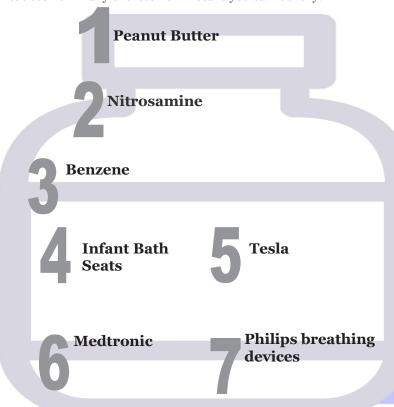
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Test Your Knowledge!

This was an interesting year in many ways, but 2022 was a banner year for all kinds of product recalls. It is rare for there to be a total of 1 billion recalled products in one year in the U.S., but in 2022 there were more than 1 billion in the first 7 months. These recalls included medical products, food, infant formula, cars, and many other consumer products.

We can think of that as good news or bad news. Of course, it is frightening when a product that we use, or were considering buying, is recalled due to serious and potentially life-threatening risks. We feel upset about others who were harmed, and it makes us feel more vulnerable as well. On the other hand, recalls mean that the system is working: Unexpected problems are identified and many lives are saved when those products are taken off the market. The sooner that happens, the better.

Let's see how many of these 2022 recalls you can identify!



- **A**. This company had 3 recalls for cardiac devices that were considered life-threatening
- **B.** Several of these products were recalled because they caused drownings
- C. 168 deaths were reported regarding these recalled products
- **D.** This product was more likely to be recalled due to salmonella than any other product
- **E.** Last year this carcinogen resulted in recalls of sunscreen. This year it resulted in recalls of dry shampoo.
- **F.** This carcinogen resulted in recalls of 3 popular drug pressure medications made by Pfizer
- **G.** More than I million of these were recalled because of risks to fingers

Answet Key: 1:D, 2:F, 3:E, 4:B, 5:G, 6:A, 7:C,

Have Ouestions?

We know it can be frustrating and confusing when you need information about a new product and all you can find are advertisements or questionable articles saying how great the product is, but not telling you useful information about the potential risks. Often, medical products are not adequately tested on both women and men, people of color, or people in your age group, but that information may not be publicly available. If you are looking for more information about a medical device, medication, or consumer product, we are happy to help! Email our helplines at info@center4research.org or <a hr

Donations from our many generous donors make it possible to respond to your specific questions for free!

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How is The Wizard of Oz related to innovative new medications you've seen advertised? See our story on page 1.

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